

Applicant: Matthias G. von Herrath
Application No.: 09/336,672
Filed: June 17, 1999
Page 3

In the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Upon entry of the present amendment, the claims will stand as follows:

Please amend claims 40, 45, 54, 58, 69, 71, 73, 75, 78 and 83 as follows:

Claims 1-39 (Cancelled)

40. (Currently Amended) An immunomodulating composition for treating autoimmune diabetes, said composition comprising one or more nucleic acid constructs encoding GAD self-antigen and IL-10 in a pharmaceutically acceptable carrier.

41. (Previously Presented) The composition of claim 40, wherein the autoimmune diabetes is type I diabetes.

Claims 42-44 (Cancelled)

45. (Currently Amended) The composition of claim 40, wherein the nucleic acid constructs further comprise[[s]] a regulatory element operatively linked to the nucleic acid encoding the self-antigen or the IL-10.

46. (Previously Presented) The composition of claim 45, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus promoter, ALV promoter, Cytomegalovirus (CMV) promoter, human Actin

Applicant: Matthias G. von Herrath
Application No.: 09/336,672
Filed: June 17, 1999
Page 4

promoter, human Myosin promoter, RSV promoter, human Hemoglobin promoter, human muscle creatine promoter and EBV promoter.

Claims 47-53 (Cancelled)

54. (Currently Amended) A method for treating autoimmune diabetes in a subject in need thereof comprising administering to the subject by peripheral administration an immunomodulatory effective amount of one or more nucleic acid constructs encoding GAD self-antigen and IL-10 in a pharmaceutically acceptable carrier, wherein transient expression of the self-antigen and the IL-10 in the subject treats the autoimmune diabetes.

55. (Previously Presented) The method of claim 54, wherein the subject is a human.

Claims 56-57 (Cancelled)

58. (Currently Amended) The method of claim 54, wherein the nucleic acid constructs further comprise[[s]] a regulatory element operatively linked to the nucleic acid encoding the self-antigen or the cytokine.

59. (Previously Presented) The method of claim 58, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus promoter, ALV promoter, Cytomegalovirus (CMV) promoter, human Actin promoter, human Myosin promoter, RSV promoter, human Hemoglobin promoter, human muscle creatine promoter and EBV promoter.

Applicant: Matthias G. von Herrath
Application No.: 09/336,672
Filed: June 17, 1999
Page 5

60. (Previously Presented) The method of claim 54, wherein the treatment comprises controlling the blood sugar of the subject.

61. (Previously Presented) The method of claim 54, wherein the treatment comprises induction of T-cells reactive to the self-antigen.

Claim 62-68 (Cancelled)

69. (Currently amended) An immunomodulating composition for treating autoimmune diabetes, said composition comprising one or more nucleic acid constructs encoding an insulin B-chain self-antigen and a cytokine selected from the group consisting of IL-10, IL-4, and a combination thereof, in a pharmaceutically acceptable carrier.

70. (Previously Presented) The composition of claim 69, wherein the autoimmune diabetes is type I diabetes.

71. (Currently Amended) The composition of claim 69, wherein the nucleic acid constructs further comprise[[s]] a regulatory element operatively linked to the nucleic acid encoding the self-antigen or the cytokine.

72. (Previously Presented) The composition of claim 71, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus promoter, ALV promoter, Cytomegalovirus (CMV) promoter, human Actin promoter, human Myosin promoter, RSV promoter, human Hemoglobin promoter, human muscle creatine promoter and EBV promoter.

Applicant: Matthias G. von Herrath
Application No.: 09/336,672
Filed: June 17, 1999
Page 6

73. (Currently Amended) A method for treating autoimmune diabetes in a subject in need thereof comprising administering to the subject by peripheral administration an immunomodulatory effective amount of one or more nucleic acid constructs encoding insulin B chain self-antigen and a cytokine selected from the group consisting of IL-4, IL-10, and a combination thereof, in a pharmaceutically acceptable carrier, wherein transient expression of the self-antigen and the cytokine in the subject treats the autoimmune diabetes.

74. (Previously Presented) The method of claim 73, wherein the subject is a human.

75. (Currently Amended) The method of claim 73, wherein the nucleic acid constructs further comprise[[s]] a regulatory element operatively linked to the nucleic acid encoding the self-antigen or the cytokine.

76. (Previously Presented) The method of claim 75, wherein the regulatory element is a promoter selected from the group consisting of Mouse Mammary Tumor Virus (MMTV) promoter, Human Immunodeficiency Virus Long Terminal Repeat (HIV LTR) promoter, Moloney virus promoter, ALV promoter, Cytomegalovirus (CMV) promoter, human Actin promoter, human Myosin promoter, RSV promoter, human Hemoglobin promoter, human muscle creatine promoter and EBV promoter.

77. (Previously Presented) The method of claim 73 wherein the treatment comprises controlling the blood sugar of the subject.

Applicant: Matthias G. von Herrath
Application No.: 09/336,672
Filed: June 17, 1999
Page 7

78. (Currently Amended) A method for treating an autoimmune process associated with autoimmune diabetes in a subject in need thereof comprising administering to the subject by peripheral administration an immunomodulatory effective amount of one or more nucleic acid constructs encoding insulin B-chain self-antigen and a cytokine selected from the group consisting of IL-4, IL-10, and a combination thereof, in a pharmaceutically acceptable carrier, wherein transient expression of the self-antigen and the cytokine in the subject treats the autoimmune process associated with the autoimmune diabetes.

79. (Previously Presented) The method of claim 78, wherein the subject is a human.

Claims 80-81 (Cancelled)

82. (Previously Presented) The method of claim 78, wherein the treatment comprises induction of T-cells reactive to the self-antigen.

83. (Currently Amended) The method of claim 73, wherein the nucleic acid constructs [[is]] are naked DNA.